## INSTITUTIONAL COMPLIANCE AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

#### I. PREAMBLE

The University of Texas Health Science Center at San Antonio ("UTHSCSA") hereby agrees to enter into this Institutional Compliance Agreement (the "Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the billing requirements of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "federal health care programs") by UTHSCSA, its physicians, employees, and other health care professionals (hereinafter collectively referred to as "physicians"), as well as all third parties with whom UTHSCSA may choose to engage to act as billing agents for UTHSCSA. UTHSCSA renders physician services through a division known as Medical Service Research and Development Plan.

Prior to the execution of this Agreement, UTHSCSA demonstrated its present responsibility by voluntarily commencing the establishment of a compliance program (also known as the "Faculty Practice Compliance Program"), which provides for corporate integrity policies and procedures and which, as represented by UTHSCSA in this Agreement, is aimed at ensuring that its participation in the federal health care programs (which includes any requests for payments) is in conformity with the statutes, regulations and other directives applicable to the programs. Therefore, pursuant to this Agreement, UTHSCSA hereby agrees to finalize the establishment of the Faculty Practice Compliance Program within one-hundred and twenty (120) days of the date of execution of this Agreement in accordance with the provisions set forth below. UTHSCSA further agrees to maintain in full operation the Faculty Practice Compliance Program for the term of this Agreement, which, at a minimum, shall always adopt as essential components the integrity obligations enumerated below. A description of the Faculty Practice Compliance Program's structure, policies and procedures is attached hereto as Attachment 1.

The University of Texas System, which is an entity related to UTHSCSA, hereby agrees that it will do nothing in its capacity as a related entity of UTHSCSA that will interfere with, or diminish, UTHSCSA's ability to discharge UTHSCSA's corporate integrity obligations under this Agreement. Accordingly, the University of Texas System will take all reasonable steps, in its capacity as a related entity of UTHSCSA, to promote compliance with the terms of this Agreement by UTHSCSA.

#### II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by UTHSCSA under this Agreement shall be five (5) years from the date of execution of this Agreement.

### III. CORPORATE INTEGRITY OBLIGATIONS

Pursuant to this Agreement, and for the duration of this Agreement, UTHSCSA will make the following integrity obligations permanent features of its Faculty Practice Compliance Program, which shall be established in accordance with the provisions below:

### A. COMPLIANCE COMMITTEE AND COMPLIANCE OFFICER

Within ninety (90) days of the date of execution of this Agreement, the President of UTHSCSA shall confirm in writing and, in accordance with section VI of this Agreement, notify OIG of the following: (i) the creation of a Compliance Committee for UTHSCSA and the appointment of its members; (ii) the delegation of authority to the Compliance Committee for the purpose of establishing and implementing the integrity obligations incorporated into the Faculty Practice Compliance Program; and (iii) the appointment of an individual to serve as UTHSCSA's Compliance Officer. The document from the President shall specify the names of those individuals appointed and their positions within the organization or outside. The members of the Compliance Committee shall, at a minimum, include the Compliance Officer, the Executive Director of UTHSCSA, and a UTHSCSA department chairman.

The Compliance Officer shall be responsible for the day-to-day compliance activities engaged in by UTHSCSA to further the integrity obligations assumed herein, as well as for any reporting obligations created under this Agreement. The Compliance Officer shall report directly to the President of UTHSCSA. The Compliance Officer shall submit the Annual Reports (or more frequently, if circumstances require) to the President of UTHSCSA, and upon the President's approval, to OIG in accordance with the provisions governing reports in this Agreement.

# B. ANNUAL REVIEW AND AUDIT OF BILLING POLICIES, PROCEDURES AND PRACTICES

UTHSCSA shall contract with an independent professional organization, such as an accounting firm, a law firm or a consulting firm (the "Annual Auditor"), with expertise in the reimbursement and billing requirements of the federal health care programs, to review and audit on an annual basis the billing policies, procedures and practices of UTHSCSA's physicians to verify that UTHSCSA's submissions for reimbursement comply with all applicable federal health care program statutes, regulations, program and carrier directives and to identify any and all instances where claims fail to meet these standards. Prior to

each review and audit, the Annual Auditor shall prepare and submit for review to OIG the work plan describing the protocols it proposes to follow in conducting the review and audit. At a minimum, the work plan must show that the review and audit are designed to determine the accuracy, validity and appropriateness of claims submitted for reimbursement to the federal health care programs and to identify patterns or significant single occurrences where claims are filed in contravention of applicable federal health program standards. The review and audit shall be aimed at ensuring that these-programs are billed appropriately for services rendered. The review shall be conducted in accordance with generally-accepted government auditing standards (also known as the "Yellow Book" standards) or other comparable standards and shall be based on a valid statistical sample of claims that is projectable to the universe of claims being audited.

For purposes of complying with this audit requirement, UTHSCSA may choose, in the alternative, to engage the auditors of the University of Texas System to perform the reviews. In such a case, UTHSCSA will engage the services of an independent, outside auditing entity to verify the accuracy of the methodologies employed by the University of Texas System auditors and the audit results. Verification may include, but will not be limited to, conducting a "probe sample." UTHSCSA will request the outside auditor to produce a report on its findings, which report shall be included in the Annual Report to OIG.

If any of these annual reviews and audits uncovers billing policies, procedures and/or practices that result in material billing deficiencies, UTHSCSA shall notify the entity in charge of processing the claim for reimbursement (such as a Medicare Part B carrier) within sixty (60) days of discovering the deficiency and take remedial steps within ninety (90) days (or such additional time as may be agreed to by the carrier or other payor) to correct the problem, including preventing the deficiency from recurring. For purposes of this Agreement, a "material billing deficiency" shall mean any isolated event or a series of occurrences that: (i) has a significant, adverse financial impact; (ii) significantly affects the veracity of the information upon which the claim is based, even if it does not have a financial impact; or (iii) might prevent UTHSCSA from submitting the claim for reimbursement (including, but not limited to, issues relating to compliance with the antikickback statute (codified at 42 U.S.C. § 1320a-7b) or the physician self-referral prohibition (codified at 42 U.S.C. § 1395nn)); and which claim lacks conformity with the programs' reimbursement principles or other applicable statutes, and the regulations and written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents, or any other agency charged with administering the affected health care program and/or its agents.

Contemporaneous to UTHSCSA's notification to the entity in charge of processing the claim for reimbursement as provided above, if any annual reviews or audits reveals material billing deficiencies, UTHSCSA shall notify OIG of: (i) its findings concerning the material billing deficiency; (ii) UTHSCSA's actions to correct such material billing

deficiency; and (iii) any further steps UTHSCSA plans to take to address such material billing deficiency and prevent it or any similar billing deficiencies from recurring.

While this reporting requirement includes occurrences having a "significant, adverse financial impact," nothing herein excuses UTHSCSA's statutory obligation as a participant in the federal health care programs to bring to a payor's attention any other billing deficiencies that may result in an overpayment by a federal health care program, however de minimis, make appropriate refunds and take any steps necessary to prevent any recurrence.

#### C. Integrity Policy

Within one-hundred and twenty (120) days of the date of execution of this Agreement, UTHSCSA shall: (i) develop and implement written policies, as more fully set forth in Attachment 1 attached hereto, regarding its commitment to the preparation and submission of accurate billings consistent with the standards set forth in the federal health care programs' regulations, procedures and guidelines or otherwise communicated by HCFA, its agents or any other agency engaged in the administration of the federal health care program and/or its agents; and (ii) provide notice of the development and implementation of such policies, as provided in section VI of this Agreement.

These policies shall be adopted by UTHSCSA and distributed to all employees, physicians and independent contractors involved in submitting or preparing any and all requests for reimbursement on behalf of UTHSCSA for submission to the federal health care programs. UTHSCSA shall post in a prominent place accessible to each employee a notice detailing its commitment to comply with all applicable federal health care program statutes, regulations and directives. A copy of the policies and notice will be available, upon request, for review by OIG.

#### D. INFORMATION AND EDUCATION PROGRAM

Within one-hundred and twenty (120) days of the date of execution of this Agreement, UTHSCSA shall: (i) develop and institute an information and education program designed to ensure that each officer, director, employee and physician of UTHSCSA is reasonably aware of all statutes, regulations and agency directives (including HCFA and its contractors, and other federal agencies charged with administering federal health care programs and their agents) relating to their individual functions within UTHSCSA, as well as the standards of business conduct that such individuals are expected to follow and the consequences, both to the individuals and to UTHSCSA, that will ensue from any violation of these requirements; and (ii) provide notice of the development and institution of the program as directed in section VI of this Agreement. This program shall be maintained for the term of this Agreement.

Pursuant to this information and education program, each officer, employee and physician shall receive at least two (2) hours of initial training regarding UTHSCSA's Faculty Practice Compliance Program. A schedule and topic outline of the training shall be included in the first Annual Report submitted to OCIG after the execution of this Agreement.

In addition to the above-mentioned training, UTHSCSA shall also implement a training program for current staff physicians, other health care professionals and clerical employees involved in preparing or submitting requests for reimbursement to the federal health care programs through UTHSCSA or its agents. This program shall provide for no less than two (2) hours of formal training on an annual basis on the following: (i) the submission of accurate bills for services rendered to patients of the federal health care programs; (ii) the personal obligation of each individual to make reasonable efforts to ensure that the information provided by the individual (either orally or in writing) relating to the care or the services rendered to patients of the federal health care programs, or otherwise provided in support of a submission for reimbursement to these programs, is accurate; (iii) applicable federal health care program reimbursement rules and statutes; and (iv) the legal sanctions for the submission of false or inaccurate information, including, but not limited to, improper billings and provide examples of improper billing practices. Such training shall also be included in the formal orientation of new employees, including staff physicians and clerical employees.

UTHSCSA shall certify that such training has been provided in its Annual Report to OIG, in accordance with sections V and VI below. Information concerning the format, dates, and a copy of the materials provided will be available, upon request, for review by OIG.

For purposes of meeting the obligations under this subsection D for the term of the first Annual Report under this Agreement, OIG shall also consider UTHSCSA's training and education activities carried out pursuant to the Faculty Practice Compliance Program since November 1, 1997.

## E. <u>CONFIDENTIAL DISCLOSURE PROGRAM</u>

Within one-hundred and twenty (120) days of the date of execution of this Agreement, UTHSCSA shall establish a confidential disclosure program enabling any employee to disclose any practices or billing procedures relating to the federal health care programs by the employee that are alleged to be inappropriate, to an identified individual not in that employee's direct chain of command. UTHSCSA shall, as part of this disclosure program, require the internal review of any disclosure that is sufficiently specific so that it: (i) permits a determination of the appropriateness of the billing practice alleged to be involved; and (ii) reasonably permits corrective action to be taken and ensure that proper follow-up is conducted. In an effort to address every disclosure, however, UTHSCSA shall, in good faith, make a preliminary inquiry for every disclosure instance to ensure they

have obtained all of the necessary information that is reasonably required to determine whether an internal review, in accordance with the language above, should be conducted. UTHSCSA shall develop an internal tracking system to record or log and follow up on all disclosures received. Upon establishing the program, UTHSCSA shall provide notice of its creation to OIG, in accordance with section VI of this Agreement.

UTHSCSA shall include in each Annual Report to OIG a summary of the communications (including the number of disclosures by employees and their dates) concerning billing practices reported as, and found to be, inappropriate under the confidential disclosure program, the results of any internal review and the follow-up on such disclosures. UTHSCSA hereby agrees to maintain such reports in a manner agreeable to OIG so that they will be readily available to OIG for a minimum of six (6) years or one (1) year longer than the duration of this Agreement.

The confidential disclosure program shall, at a minimum, provide for toll free telephone lines to be maintained by UTHSCSA and made known and available to all directors, officers, employees, physicians, contractors and patients twenty-four hours-a-day, seven days-a-week for the purpose of making any disclosures regarding compliance with the Faculty Practice Compliance Program, the obligations in this Agreement and UTHSCSA's overall compliance with federal and state standards.

UTHSCSA shall select the manner in which disclosures are received, processed and resolved. The disclosing individual's identity may be requested, but shall not be required. Anonymity shall not be discouraged.

## F. DEALING WITH EXCLUDED OR CONVICTED PERSONS OR ENTITIES

UTHSCSA shall implement a written internal operating policy that UTHSCSA shall not knowingly employ (either as a bona fide employee or as an independent contractor) with or without pay, an individual or entity that is listed by a federal agency as excluded, suspended or otherwise ineligible for participation in federal programs to hold any position or render any services for which the individual's or entity's compensation or the services rendered by the individual or entity are paid in whole or in part, directly or indirectly by a federal health care program or otherwise with federal funds. In order to carry out the policy, UTHSCSA shall make a reasonable inquiry into the status of any potential employee or independent contractor. Such a reasonable inquiry shall be made during the hiring process and shall include, at a minimum, a review of OIG's Cumulative Sanctions Report and the General Services Administration's ("GSA's") List of Parties Excluded from Federal Procurement and Non-Procurement Programs. Among other places, these reports can be found on the "Internet" at www.dhhs.gov/progorg/oig and www.arnet.gov/epls, respectively.

Additionally, UTHSCSA will remove from responsibility for, or involvement with, UTHSCSA's federal health care program business operations any employee who becomes suspended or is proposed for exclusion during the individual's employment with UTHSCSA until the resolution of such suspension or proposed exclusion. In addition, if any employee of UTHSCSA is charged with a criminal offense relating to its federal health care program business, UTHSCSA will remove that employee immediately from responsibility for, or involvement with, UTHSCSA's federal health care program affairs. If an employee is convicted or debarred, UTHSCSA shall remove this individual from any position for which the individual's salary or the services rendered by the individual are paid in whole or in part, directly or indirectly by the federal health care programs or otherwise with federal funds. UTHSCSA shall notify OIG of each such personnel action taken and the reasons therefore, within thirty (30) days of the action.

UTHSCSA shall not knowingly allow, or cause to be allowed, any person convicted in any local, state or federal court of any felony involving health care matters to hold the position of director, officer or manager of UTHSCSA, or any of its agents either through an employment agreement or an independent contract.

Should UTHSCSA discover that it has employed an individual in contravention of this subsection F. UTHSCSA will have thirty (30) days to take the necessary steps to cure the problem, in accordance with this subsection F, section VI below and federal due process laws.

## IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine UTHSCSA's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) UTHSCSA's compliance with the terms of this Agreement; and (ii) UTHSCSA's compliance with the requirements of the federal health care programs. The documentation described above shall be made available by UTHSCSA at all reasonable times for inspection, audit and reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of UTHSCSA's employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. UTHSCSA agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request.

#### V. ANNUAL REPORTS

UTHSCSA shall make annual reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures UTHSCSA has taken to implement the Faculty Practice Compliance Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include the following information:

- 1. In the first Annual Report, copies of the document or documents that comprise UTHSCSA's Faculty Practice Compliance Program established under this Agreement, as adopted by UTHSCSA and implemented by the Compliance Committee. For subsequent years, UTHSCSA shall note in the report any amendments or revisions to the Program documents made during the year covered by the Annual Report.
- 2. Copies of any revisions or amendments made to the billing policies, procedures and practices used or followed in the generation of claims or bills to the federal health care programs made during the year covered by the Annual Report pursuant to section III.B and Attachment 1 of this Agreement.
- A detailed description of the findings made during the reviews and audits conducted pursuant to section III.B of this Agreement relating to the year covered by the Annual Report, copies of the disclosure or notice documents made by UTHSCSA pursuant to that section, and a description of the corrective steps and proof of refund to the pertinent payor (where applicable).
- 4. Any revisions or amendments made during the year covered by the Annual Report to the Integrity Policy developed pursuant to section III.C of this Agreement.
- 5. A description of the Information and Education Program implemented pursuant to section III.D of this Agreement and a summary of the activities engaged in, in furtherance of this program, including a schedule, a topic outline of the training sessions and a list of the participants organized by department or division.
- A summary of communications (including the number of disclosures by employees and their dates) received through the Confidential Disclosure Program established pursuant to section III.E concerning billing practices reported as, and found to be inappropriate, and the results of all investigations and internal reviews, as well as any follow up on such disclosures.
- 7. A summary of the background inquiries conducted pursuant to section III.F above on which any personnel actions (other than hiring) were taken as a result of these inquiries.

- 8. A statement about any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that UTHSCSA has committed a crime or has engaged in fraudulent activities, or any requests (whether voluntary or compulsory) for the production of documents, information or testimony made to UTHSCSA (or its officers, employees or physicians in connection with their relationship to UTHSCSA) by a federal or state agency, which relates to a federal health care program. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or request.
- 9. The names of UTHSCSA's officers and Compliance Committee members.
- 10. A written certification from the President of UTHSCSA indicating that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

Where applicable, the Annual Report shall include a statement that, to the best of UTHSCSA's knowledge, no events subject to the reporting requirements identified above occurred, other than those described in the Annual Report. UTHSCSA agrees to maintain all information (including supporting documentation) relating to such reports on its premises and arranged by report year so that they will be readily available to OIG for a minimum of six (6) years or one (1) year longer than the duration of this Agreement.

The period covered by the Annual Report shall be twelve (12) months commencing on September 1 and ending on August 31 of the following calendar year. Each Annual Report shall be submitted to OIG no later than November 1 following the end of the period covered by the Annual Report. The first Annual Report shall be due on November 1, 1999.

#### VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

ATTENTION:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW Cohen Building, Room 5527 Washington, DC 20201 Ph. 202.619.2078 Fax 202.205.0604

ATTENTION:

President

The University of Texas Health Science Center at San Antonio

7703 Floyd Curl Drive

San Antonio, Texas 78284-7862

Ph. 210.567.2050 Fax 210.567.2025

#### VII. DOCUMENT AND RECORD RETENTION

UTHSCSA shall maintain for inspection documents and records relating to reimbursement from the federal health care programs for a period of six (6) years following the execution of this Agreement or one (1) year longer than the duration of this Agreement.

#### VIII. BREACH AND DEFAULT

UTHSCSA's compliance with the terms and conditions in this Agreement shall constitute an element of UTHSCSA's present responsibility with regard to participation in the federal health care programs. Full and timely compliance by UTHSCSA shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by UTHSCSA. As stated below in section X of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

## A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, UTHSCSA and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of specific monetary penalties (hereinafter referred to as "stipulated penalties") in accordance with the following provisions.

- 1. A stipulated penalty of \$2,500 for each day UTHSCSA fails to comply with any of the following, which stipulated penalty shall begin to accrue one day after the date the obligation becomes due:
  - a submission of the complete Annual Report, in accordance with the requirements in section V, by November 1 of the applicable year;

- b. appointment of a Compliance Officer within ninety (90) days of the date of execution of this Agreement;
- c. appointment of a Compliance Committee within ninety (90) days of the date of execution of this Agreement;
- d. make available to all employees and patients a toll-free telephone line pursuant to the Confidential Disclosure Program within one-hundred and twenty (120) days of the execution of this Agreement.
- 2. A stipulated penalty of \$2,500 for each day UTHSCSA fails to comply by having in force during the term of this Agreement any of the following, which stipulated penalty shall begin to accrue on the date of OIG's notice of noncompliance or as otherwise indicated in OIG's notice, in accordance with section VIII.B below.
  - a. the Faculty Practice Compliance Program adopted pursuant to section III of this Agreement;
  - b. the Compliance Committee and the Compliance Officer, discharging their respective duties, as required under section III.A of this Agreement;
  - c. the Education and Information Program required under section III.D of this Agreement;
  - d. the Confidential Disclosure Program required under section III.E of this Agreement.
- A stipulated penalty of \$2,500 for each day UTHSCSA fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review rights set forth in section IV of this Agreement, which stipulated penalty shall begin to accrue on the date UTHSCSA fails to grant reasonable access.
- 4. A stipulated penalty of \$1,500 for each day UTHSCSA knowingly employs in a position related to the federal health care programs (as specified in section III.F above) an individual after that individual has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)), which stipulated penalty shall begin to accrue on the date of OIG's notice of noncompliance or as otherwise indicated in OIG's notice, in accordance with section VIII.B.

5. A stipulated penalty of \$1,000 for each day UTHSCSA fails to comply with any other requirement in this Agreement, which is not covered by provisions 1, 2, 3 and 4 of section VIII.A of this Agreement, which stipulated penalty shall begin to accrue on the date of OIG's notice of noncompliance in accordance with section VIII.B.

#### B. PAYMENT OF STIPULATED PENALTIES

Upon finding that UTHSCSA has failed to comply with any of the above-enumerated obligations, OIG may choose to demand payment of the stipulated penalties above. To effectuate the demand, OIG shall notify UTHSCSA of: (i) UTHSCSA's failure to comply; and (ii) OIG's exercise of its contractual right to demand payment of the stipulated penalties payable under this Agreement (this notification is hereinafter referred to as the "Demand Letter").

Within ten (10) days of receipt of the Demand Letter, UTHSCSA shall respond by either: (i) curing the breach to OIG's satisfaction, paying the applicable stipulated penalties and notifying OIG of its corrective actions; or (ii) sending in writing to OIG a request for a hearing before an HHS administrative law judge to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth in section VIII.D of this Agreement. UTHSCSA's election of the contractual right herein to seek review of OIG's noncompliance determination shall not preclude UTHSCSA from also choosing to pay the applicable stipulated penalties at any time after receiving the Demand Letter. Failure to respond to the Demand Letter shall be considered a material breach of this Agreement and shall be grounds for exclusion under section VIII.C below.

Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI of this Agreement.

#### C. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If UTHSCSA engages in conduct that OIG considers to be a material breach of this Agreement, OIG may seek exclusion of UTHSCSA from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon making its determination, OIG shall notify UTHSCSA of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this letter shall be referred to hereinafter as the "Notice of Material Breach and Intent to Exclude"). UTHSCSA shall have thirty-five (35) days from the date of the letter to:

1. demonstrate to OIG's satisfaction that UTHSCSA is in full compliance with this Agreement;

- 2. cure the alleged material breach; or
- demonstrate to OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that UTHSCSA has begun to take action to cure the material breach and that it shall pursue such action with due diligence. UTHSCSA shall, at this time, submit a timetable for curing the material breach for OIG's approval.

If at the conclusion of the thirty-five-day period (or other specific period as subsequently agreed by OIG and UTHSCSA), UTHSCSA fails to act in accordance with provisions 1, 2 or 3 above, OIG will exclude UTHSCSA from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). OIG shall notify UTHSCSA in writing of its determination to exclude UTHSCSA (this letter shall be referred to hereinafter as the "Exclusion Letter").

Notwithstanding any provisions in Chapter 42 of the Code of Federal Regulations, the exclusion shall take effect thirty (30) days from the date of the Exclusion Letter unless UTHSCSA exercises its contractual right to seek review of OIG's exclusion determination by requesting a hearing before an administrative law judge as provided in section VIII.D below. In the event UTHSCSA requests such a hearing, the exclusion shall not be effective until the issuance of an administrative law judge's decision supporting OIG's exclusion determination. The exclusion of UTHSCSA shall have national effect and will also apply to all other federal procurement and non-procurement programs.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material billing violation, take corrective action and pay the appropriate refunds, as provided in section III.B of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VIII.A of this Agreement; or (iii) failure to respond to a Demand Letter concerning the payment of stipulated penalties in accordance with section III.B above.

In connection with OIG's determination to exclude UTHSCSA pursuant to this provision, UTHSCSA shall have the right to dispute OIG's determination in accordance with the agreed upon provisions set forth in section VIII.D of this Agreement.

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#### D. DISPUTE RESOLUTION

Upon OIG's delivery to UTHSCSA of its Demand Letter or of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, UTHSCSA shall be afforded review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of stipulated penalties or to seek

exclusion shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within ten (10) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this section shall be: (i) whether, on the date of the Demand Letter, UTHSCSA was in compliance with the obligations in this Agreement for which OIG demands payment; (ii) whether UTHSCSA failed to cure; (iii) whether the alleged noncompliance could have been cured within the ten-day period; and (iv) the period of noncompliance. For purposes of paying stipulated penalties under this Agreement, and if UTHSCSA chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the administrative law judge's decision shall give rise to UTHSCSA's obligation to pay. Thus, payment will be due twenty (20) days from the day the administrative law judge's decision is mailed.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be: (i) whether UTHSCSA was in material breach of one or more of its obligations under this Agreement; (ii) whether the alleged material breach was continuing on the date of the Exclusion Letter; (iii) whether, as of the date of the Exclusion Letter, UTHSCSA had failed to cure; and (iv) whether the alleged material breach could have been cured within the thirty-five-day period or such other period as agreed to in writing between UTHSCSA and OIG. For purposes of the exclusion herein agreed to, in the event of a material breach of this Agreement, an administrative law judge's decision finding in favor of OIG shall be deemed to make the exclusion effective, at which time OIG may proceed with its exclusion of UTHSCSA.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, OIG shall have the burden of going forward and the burden of persuasion with respect to the issue of whether UTHSCSA was in compliance (for stipulated penalties) or in material breach (for exclusion) and with respect to the period of noncompliance or material breach. UTHSCSA shall bear the burden of going forward and the burden of persuasion with respect to the issue of whether, as of the date of the Demand Letter or the Exclusion Letter, UTHSCSA cured the alleged noncompliance or material breach, and with respect to the issue of whether the alleged noncompliance or material breach could have been cured during the specified period. The burden of persuasion will be judged by a preponderance of the evidence.

The review by an administrative law judge provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the administrative law judge's decision shall be considered final for the purposes of this Agreement.

All notices required under any of the aforementioned proceedings shall be given to OIG and UTHSCSA in accordance with section VI of this Agreement.

#### IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, UTHSCSA and OIG agree as follows:

- 1. this Agreement shall be binding on the successors, assigns and transferees of UTHSCSA;
- 2. this Agreement shall become final and binding only upon signing by each respective party hereto;
- 3. any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement; and
- 4. the undersigned UTHSCSA signatories represent and warrant that they are authorized to execute this Agreement. The undersigned United States signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

## ON BEHALF OF THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

JOHN P. HOWE, III. M.D.

President of The University of Texas Health Science Center at San Antonio <u>6/9/98</u>
DATE

FREDERICK ROBINSON, ESQUIRE

Counsel for The University of Texas Health

Science Center at San Antonio

### ON BEHALF OF THE UNIVERSITY OF TEXAS SYSTEM

K. RAY FARABEE, ESQ.
Vice Chancellor and General Counsel of the
University of Texas System

# ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS, ESQUIRE

Assistant Inspector General for Legal Affairs

Office of Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services